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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,740	04/26/2005	Pieter Johan Peeters	PRD-2008-USPCT1	3700
27777	7590	11/17/2008		EXAMINER
PHILIP S. JOHNSON				SAOUD, CHRISTINE J
JOHNSON & JOHNSON				
ONE JOHNSON & JOHNSON PLAZA			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,740	<b>Applicant(s)</b> PEETERS ET AL.
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 October 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 and 6-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1668)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION*****Response to Amendment***

Applicant's amendment filed 21 October 2008 has been received and entered. Claims 5 and 11-34 have been canceled and claims 1, 3, 4, 8 and 10 have been amended. Claims 1-4 and 6-10 are currently pending and under examination in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 21 October 2008 have been fully considered but are not persuasive.

***Drawings***

The drawings were received on 21 October 2008. These drawings are not acceptable. There is a minor error in Figure 5; the top panel is not labeled with "A". This is required because the Brief Description of the Figures refers to Figure 5A-5C and there is no "A". Figures 1-4 are acceptable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 4, 8 and 10 have been amended such that they recite "protein having an amino acid sequence SEQ ID NO:46", "said polynucleotide comprising a nucleic acid sequence SEQ ID NO:45", "consisting of a nucleic acid sequence SEQ ID NO:45", "said protein having an amino acid sequence SEQ ID NO:46". The use of the article an/a implies that there are multiple sequences which are encompassed by the claims (including fragments of the recited sequences). The instant specification fails to describe all fragments and sequences which can be made from SEQ ID NO:45 and 46 such that the protein or protein encoded by the nucleic acid modulates corticotropin releasing hormone. The instant specification fails to describe any polypeptides other than the polypeptide of SEQ ID NO:46. First, the instant specification teaches a single example of a polypeptide (SEQ ID NO:46), and fails to teach any variation from the amino acid sequence of SEQ ID NO:46. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein which has the amino acid sequence of SEQ ID NO:46. The subject matter that is claimed is described above. First, a determination of the level of predictability in

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the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to nucleic acids encoding a polypeptide which has a sequence SEQ ID NO:46. The claims are not limited to any particular polypeptide, in that the claims encompass multiple proteins in the form of fragments as implied by the use of the article "an". The specification only describes a single polypeptide and fails to teach or describe any other molecules which meet the functional limitations of the claims. There is a lack of guidance or teaching regarding structure and function of the polypeptide because there is only a single example of a polypeptide provided in the specification and because there is no guidance found in the prior art for this specific polypeptide, including a lack of disclosure of activity for the polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for possibly the polypeptide of SEQ ID NO:46. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear,

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concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the specification teaches a single embodiment. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al.

Strausberg et al. (GENEMBL accession no. BC005546) teach a nucleic acid molecule which has 100% nucleic acid sequence identity to SEQ ID NO:45. Because the sequence is 100% identical, it would inherently encode the protein recited in the claims, including a protein with the recited activity. Therefore, Strausberg et al. anticipates claims 1-4.

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Applicant argues that Strausberg et al. was an online publication on 11 December 2002 and that the instant application has an effective priority date of October 31, 2002 and therefore, Strausberg et al. is not valid prior art.

Applicants arguments are not found persuasive because the Strausberg et al. reference was submitted on the IDS filed 26 April 2005 and the IDS filed by Applicant provides the date of April 5, 2001. This clearly provides evidence that the sequence was released as of 05 April 2001 and constitutes prior art under 102(b), absent evidence to the contrary.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausberg et al..

The disclosure of Strausberg et al. is as described above. The reference fails to teach vectors and host cells expressing encoded protein. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to insert the nucleic acid molecule of Strausberg et al. into a vector and a host cell in order to recombinantly produce the protein encoded by

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the nucleic acid. One would be motivated to put the nucleic acid molecule into a vector and recombinantly produce the encoded protein, including using regulatory sequences, because this was routine in the art at the time of the instant invention for further elucidating the significance of the nucleic acid molecule which was taught by Strausberg et al. One would have a reasonable expectation of success in doing this because at the time the invention was made, the recombinant production of proteins was old and well known in the art. Therefore, the invention as a whole would have been *prima facie* obvious at the time it was made, absent evidence to the contrary.

Applicant argues that Strausberg et al. is not prior art. Applicant's argument has been fully considered, but is not persuasive for the reasons provided above.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/  
Primary Examiner, Art Unit 1647